Los Alamos National Laboratory

Laboratory Implementation Requirements LIR 308-00-04.1 (Reissued)

Effective Date: October 1, 2001 (Rissued October 18, 2004) Mandatory Document

#### 1.0 INTRODUCTION

Note: Click here for Lessons Learned that may apply to the requirements contained in this LIR.

Los Alamos National Laboratory (the Laboratory, LANL) procures items and services in support of its mission. The performance of these items and services are critically important to the success of the work in which they are used, affecting issues of requirement performance, safety, security, and cost. When such critically important issues exist, care must be exercised to ensure the items and services meet form, fit, function, and intended performance. The requirements contained in this LIR shall be implemented when procuring items and services and are established to complement the following Laboratory requirement documents:

This document complements the following Laboratory official documents:

LPR 300-00-00 "Integrated Safety Management"

LPR 308-00-00 "Quality"

LIR 230-03-01 "Facility Management Work Control"

LIR 230-01-02 "Graded Approach for Facility Work"

LIR 300-00-01 "Safe Work Practices"

LIR 300-00-04 "Laboratory Training: A Graded and Systematic Approach to a Qualified Workforce"

LIR 308-00-02, "Laboratory Records Management"

This document also supersedes Notice 0098 "New Requirements for Procurement LIR Implementation Schedule."

Implementation of the requirements contained in this LIR shall be effective upon the date(s) listed in Section 5.0 below.

#### 2.0 IN THIS DOCUMENT

Section 8 of this document provides roles and responsibilities, which define who and what the responsible persons or organizations are required to do. Section 9 provides the specific requirements in the execution of persons' or organizations' roles and responsibilities.

Section	Sub-	Title
	Section	
3.0		Purpose
4.0		Scope and Applicability
5.0		Implementation Schedule
6.0		Definitions
7.0		Precautions and Limitations
8.0		Roles and Responsibilities
	8.1	Responsible Line Management
	8.2	Requestors

Los Alamos National Laboratory

Laboratory Implementation Requirements LIR 308-00-04.1 (Reissued)

Effective Date: October 1, 2001 (Rissued October 18, 2004)

Mandatory Document

Section	Sub-	Title
	Section	
	8.3	BUS Procurement
	8.4	BUS Materials Management (BUS-4)
	8.5	Institutional Quality Management (PS-1/IQM)
	8.6	Systems, Engineering, and Maintenance (FWO-SEM)
9.0		Implementation Requirements
	9.1	Procurement Quality Management Level (ML)
	9.2	Procurement Methods
	9.3	Specifications for Items or Services
	9.4	Supplier Qualification and Performance
	9.5	Inspection and Acceptance
	9.6	Control of Purchased Items or Services
10.0		Records
11.0		Ownership
12.0		References

#### 3.0 PURPOSE

This LIR defines requirements that shall be implemented for procurement actions and processes. Such actions/processes shall be engaged and documented with a level of rigor, depth, and detail, using a graded approach, to ensure (1) items or services meet established expectations and perform as specified and (2) historical records are maintained to demonstrate rigor of the procurement process, qualification of the supplier, and conformance to use.

#### 4.0 SCOPE AND APPLICABILITY

This LIR shall apply to all Laboratory divisions, programs, organizations, personnel, and to all subcontractors under the terms and conditions of their individual contracts who procure items or services that, when in use, have critical performance expectations affecting mission, safety and health, environmental protection, and/or security and safeguards.

#### 5.0 IMPLEMENTATION SCHEDULE

Implementation shall be accomplished by July 2003. The following key milestones shall be met.

- All purchases from Hazard Category 2 and 3 nuclear facilities no later than February 2003
- All purchases from less than Hazard category 3 nuclear facilities no later than May 2003
- All remaining purchases no later than July 2003

## **6.0 DEFINITIONS**

Commercial Grade Item: An item, which is not subject to unique design requirements or specifications and is readily available in a published catalog.

Conformance Documentation: An official record of observed characteristics that document confirmation that items meet specification, which may include Certificate of Conformance provided by the supplier;

Los Alamos National Laboratory

Laboratory Implementation Requirements LIR 308-00-04.1 (Reissued)

Effective Date: October 1, 2001 (Reissued October 18, 2004)

Mandatory Document

Certified Material Test Report provided by the supplier; or Acceptance Report based on receipt inspection or testing.

*Item:* An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, data, or support systems.

Qualified and Authorized Personnel: An employee, authorized by the responsible line-management, who has the academic credentials, certifications, and/or work experience to perform any one of the following: design and/or define specifications, perform inspection or acceptance testing, or assess supplier qualifications. With respect to inspection or acceptance testing, experience or education in a relevant discipline is required.

**Guidance Note**: See LIR 300-00-04 "Laboratory Training: A Graded and Systematic Approach to a Qualified Workforce." For assistance in determining or developing an employee's qualifications for performing supplier assessments or inspection/test activities, contact the Institutional Quality Management (PS-1/IQM).

*Requestor:* Qualified and authorized person who determines technical or performance specifications, codes and standards that apply, and quality-related expectations.

Service: An activity that directly engages the time and effort of a subcontractor to perform an identifiable task rather than to furnish an end item.

Source Inspection: Planned and documented inspections performed by the requestor's representative at the manufacturer or supplier's location, usually during the manufacturing or procurement process and prior to shipment.

Supplier: A company or organization that manufactures and/or distributes (wholesale or retail) items or that provides services.

## 7.0 PRECAUTIONS AND LIMITATIONS

The "Nuclear Safety Management Rule," (10CFR 830, Subpart A) states Laboratory personnel (including those responsible for supplying items and/or services) who conduct activities that affect or may affect the safety of a nuclear facility or activity are required to procure in accordance with the quality assurance criteria set forth in 10CFR 830.122.

The University of California contract with the Department of Energy includes DOE order 414.1A, "Quality Assurance." The requirements of the order are the same as 10CFR 830.122 and shall apply to activities that affect or may affect facility and/or operational safety.

**Guidance Note:** Use of requirements in this LIR will not, by itself, assure that quality items and services are procured. Other quality criteria, such as design, work processes, and assessment, may need to be implemented to ensure items and services perform as intended.

#### 8.0 ROLES AND RESPONSIBILITIES

## 8.1 Responsible Line Management shall

• Ensure procurements meet the rigor, depth, and detail to assure form, fit, function, and performance expectations.

Los Alamos National Laboratory

Laboratory Implementation Requirements LIR 308-00-04.1(Reissued)

Effective Date: October 1, 2001 (Reissued October 18, 200)

Mandatory Document

- Ensure qualified and authorized personnel determine technical and performance specifications, perform acceptance and test procedures, and validate expected item/service performance.
- Request variances in accordance with LIR 301-00-02 "Variances and Exceptions to Laboratory Operations Requirements."

### 8.2 Requestors shall

- Determine procurement-quality management level and procurement method for each purchase.
- Identify to BUS Procurement when procurement actions are subject to 10CFR830.122 "Quality Assurance Requirements."
- Prepare procurement technical or performance specifications and inspection/acceptance criteria.
- Coordinate with BUS Procurement to accomplish the purchase.
- Use qualified suppliers. See evaluated suppliers list to determine the suppliers that are qualified. (http://www.esh.lanl.gov/~esh14/Homepage/Links/forms/qsl.pdf)
- Ensure items are inspected and accepted per defined criteria.
- Input to the LANL supplier performance system the determination of item or service acceptability.
- Ensure storage, control, and use of items assures form, fit, and function.
- Retain records to assure historical verification of form, fit, function, and/or expected performance.

#### 8.3 BUS Procurement shall

- Advise the requestor to assure procurement quality requirements are included in procurement documents.
- Communicate quality requirements and flow-down clauses to the supplier and ensure such requirements flow down to their subcontractors or suppliers as required.
- Ensure award to qualified suppliers.
- Participate in review and re-qualification of suppliers.

## 8.4 BUS Materials Management (BUS-4) shall

- Notify the requestor or designee upon receipt of the items requiring inspection or acceptance testing.
- Ensure storage, control, and delivery of items per requestor instructions.

Los Alamos National Laboratory

Laboratory Implementation Requirements LIR 308-00-04.1(Reissued)

Effective Date: October 1, 2001 (Reissued October 18, 2004)

Mandatory Document

# 8.5 Institutional Quality Management (PS-1/IQM) shall

- Upon request, assist in development of quality documentation, to include specifications and inspection/acceptance test plans.
- Establish and maintain LANL suspect/counterfeit evaluation tools.
- Establish, maintain, and provide the LANL supplier qualification system for on-site or desktop supplier assessment. Upon request, support requestors and BUS Procurement in such assessments.
- Maintain the LANL Institutional Evaluated Supplier List (IESL), supplier performance records, and inspection/acceptance test results.
- Establish and maintain the LANL supplier performance system. Analyze, trend, and report supplier performance data to BUS Procurement.
- Ensure supplier qualifications are validated, as required.

# 8.6 Receipt Inspection Team (RIT)(PS-1/IQM) shall

- Perform inspection and/or test procedures as specified by the requestor.
- Document conformance or non-conformance to specifications.
- Update the LANL supplier performance system.

## 8.7 Systems, Engineering, and Maintenance (FWO-SEM) shall

- Maintain LANL standard construction specifications for items.
- Upon request, support requestors to develop technical specifications.
- Maintain and, upon request, provide a LANL standards-setting process to develop and document programmatic standard specifications (e.g., glove boxes).

#### 9.0 IMPLEMENTATION REQUIREMENTS

Requestors shall determine the technical or performance specifications, codes and standards that apply, and quality requirements associated with a given procurement. Processes established to meet these requirements shall ensure:

- The item or service is correctly specified and effectively communicated to the supplier.
- Qualification of suppliers is documented commensurate with the management level of the procurement action.
- Conformance to specifications is established, documented, and provided for institutional tracking and trending.
- Storage and control of items maintains conformance until placed into service.
- Inspection for and control of suspect or counterfeit items, when a concern exists.

Los Alamos National Laboratory

Laboratory Implementation Requirements LIR 308-00-04.1(Reissued)

Effective Date: October 1, 2001 (Reissued October 18, 2004)

Mandatory Document

Persons or organizations engaging the procurement process shall use institutional systems and processes per their the applicability to the task as defined by the institutional system/process owner. The institutional owners of systems and/or processes are identified in this LIR.

**Guidance Note:** A diagram of the procurement process identifying key interfaces and decision points to meet various quality specifications is provided at <u>Procurement Process Information Paths (Flowcharts)</u>. It includes active links to URLs with supporting instructions or contacts.

# 9.1 Procurement Quality Management Level (ML)

Procurements shall be graded with respect to the impact an item or service has on Laboratory safety, health, environmental, security, and/or mission consequences. Grading shall be in accordance with LIR 230-01-02 (<a href="http://labreq.lanl.gov/pdfs/ops/lir/LIR2300102.pdf">http://labreq.lanl.gov/pdfs/ops/lir/LIR2300102.pdf</a>) "Graded Approach to Facility Work." The ML determination for each item or service shall be specific to each procurement action.

**Guidance Note:** Guidance for determining an ML are found in LIG 230-01-02, (<a href="http://labreq.lanl.gov/pdfs/ops/lig/lig2300102.pdf">http://labreq.lanl.gov/pdfs/ops/lig/lig2300102.pdf</a>). The ML of the overall system or process may differ from the item or service. For example, a bolt may be a commercial grade item (ML 3 or 4) even if it fits on a glove box or in a HVAC system that is considered ML 1.

#### 9.2 Procurement Methods

Multiple methods are available for accomplishing procurements. The requestor in concert with BUS Procurement shall determine the appropriate method for the specific item or service.

#### 9.2.1 Purchase Cards

Purchase Card shall be limited to commercial grade or catalog items and services that do not require conformance documentation. Additional information is available at <a href="http://businternal.lanl.gov/bus5/pcard/pc1.htm">http://businternal.lanl.gov/bus5/pcard/pc1.htm</a>

# 9.2.2 Just-in-Time (JIT)

JIT shall be limited to commercial grade or catalog items or services. Instructions for the specific conformance documentation shall be included in the special instructions section of the JIT order form (<a href="http://jtprod.lanl.gov:80/">http://jtprod.lanl.gov:80/</a>). The only conformance documentation that can be requested on the JIT System shall be as follows:

- Certificates of Conformance (C of Cs),
- Certificate of Proof Test (limited to Hoisting, Lifting, and Rigging Items),
- Heat Number Stamping (limited to metallic components and raw materials),
- Certified Material Test Reports (CMTRs),
- Calibration Certification, and/or
- Receipt Inspection by the Receipt Inspection Team (RIT)(PS-1/IQM).

Los Alamos National Laboratory

Laboratory Implementation Requirements LIR 308-00-04.1(Reissued)

Effective Date: October 1, 2001 (Reissued October 18, 200) Mandatory Document

**Guidance Note:** Additional information is available at <a href="http://jtprod.lanl.gov:80/">http://jtprod.lanl.gov:80/</a>).

# 9.2.3 Purchase Request (PR) or Task Order (TO) Releases

PR or TO releases shall be the preferred method for procurement actions at the ML1 and 2 levels, and for ML 3 noncommercial grade items or services. Form 838C, "Quality Assurance Supplement, (<a href="http://enterprise.lanl.gov/forms/838c.pdf">http://enterprise.lanl.gov/forms/838c.pdf</a>) shall be submitted with the PR to specify level of rigor, depth, and documentation. When required, a separate inspection/test plan identifying characteristics to be inspected or acceptance tested, including tolerances and rejection criteria, shall be included. Additional information is available at <a href="http://labreq.lanl.gov/pdfs/ops/lir/LIR2200301.pdf">http://labreq.lanl.gov/pdfs/ops/lir/LIR2200301.pdf</a>

**Guidance Note:** A/E and design services may be accessed through PM Division captive A/E subcontracts. Guidance regarding standards and specifications for such services are available at http://labreq.lanl.gov/pdfs/ops/lir/LIR2200301.pdf

#### 9.2.4 Fabrication Work Releases

Conformance documentation, consistent with the ML determination, shall be created and maintained by the requestor.

**Guidance Note:** Fabrication Work Releases under blanket procurements for fabrication are available for mechanical (machine shop services) and printed circuit board fabrication from an authorized list of subcontractors. Forms and additional information are available at <a href="http://businternal.lanl.gov/bus5/reqguide/specproc/specproc.htm">http://businternal.lanl.gov/bus5/reqguide/specproc/specproc.htm</a>

## 9.2.5 Local Supplier Agreement (LVA)

LVA shall be limited to commercial grade or catalog items that do not require conformance documentation.

#### 9.3 Specifications for Items or Services

Specifications shall document clear and accurate descriptions of technical or performance expectations and quality requirements for items or services. Specifications shall be detailed to assure form, fit, function, and intended performance. The depth and detail shall be based upon the ML determination.

Guidance Note: Definition of the types of specifications and their typical use in procurement may be found in the Requestor's Guides (<u>Using a Purchase Request - Work Description (SOW)</u>). A number of standard specifications for engineered systems and components are available through the LANL Construction Specifications Manual found at (<a href="http://www.lanl.gov/orgs/f/f6/pubf6stds/conspec/pdfs/intro.pdf">http://www.lanl.gov/orgs/f/f6/pubf6stds/conspec/pdfs/intro.pdf</a>). FWO-SEM administers a process to establish standard specifications and can provide systems engineering support for developing technical specifications. Contact information may be found at (<a href="http://www.lanl.gov/f6stds/pubf6stds/programdirection.html">http://www.lanl.gov/f6stds/pubf6stds/programdirection.html</a>).

Los Alamos National Laboratory

Laboratory Implementation Requirements LIR 308-00-04.1 (Reissued)

Effective Date: October 1, 2001 (Reissued October 18, 2004)

Mandatory Document

# 9.4 Supplier Qualification and Performance

Suppliers shall be assessed and qualified to provide items or services by qualified and authorized personnel. The rigor and depth of supplier assessment shall be graded commensurate with the ML determination. Approved Laboratory supplier-assessment processes shall be established and used. The list of evaluated suppliers is available at

(http://www.esh.lanl.gov/~esh14/Homepage/Links/forms/qsl.pdf).

**Guidance Note:** (PS-1/IQM) can assist in determining appropriate supplier assessment processes and qualifications of personnel to perform such assessments.

Supplier performance shall be tracked using the LANL supplier performance system maintained by (RIT)(PS-1/IQM) to provide data for review and re-qualification of suppliers to BUS Procurement. The maximum elapsed time for re-evaluation of active suppliers shall be three years and the evaluation criteria shall be identified in group/project procedures, work instructions, and/or evaluation plans.

## 9.5 Inspection and Acceptance

Qualified and authorized personnel shall perform inspection and acceptance testing. The process shall ensure required conformance documentation. Methods of acceptance shall be defined by the requestor and shall be based on the technical or performance specifications of the item. Results of the inspection/test shall be input to the LANL supplier performance system.

**Guidance Note:** Typical methods include, but are not limited to one or more of the following.

- Receipt inspection (technical or peer review of documentation from the supplier, physical inspection, review and acceptance of certification documentation)
- Post-installation testing
- Surveillance or audits of supplier
- Source inspection

In the event suspect or counterfeit items are a concern, the requestor shall ensure inspection includes suspect/counterfeit criteria. If items are found to be suspect or counterfeit, storage shall preclude use, and disposition shall ensure the item is not reintroduced for use.

**Guidance Note:** (RIT)(PS-1/IQM) can assist with instructions or processes to identify and handle suspect/counterfeit items.

Nonconforming items that are identified at any point during the acceptance process shall be documented, evaluated, segregated, and controlled until the required technical requirements are shown to have been met through repair, reject, scrap, or use-as-is.

**Guidance Note:** Additional information is available at <a href="http://bus.lanl.gov/bus5/reqguide/reqguide.htm">http://bus.lanl.gov/bus5/reqguide/reqguide.htm</a> or from (RIT)(PS-1/IQM).

Los Alamos National Laboratory

Laboratory Implementation Requirements LIR 308-00-04.1(Reissued)

Effective Date: October 1, 2001 (Reissued October 18, 2004)

**Mandatory Document** 

#### 9.6 Control of Purchased Items

• Items pending use or other disposition shall be stored such that controls for identification, handling, storage, and packaging assure form, fit, and function until placed into use.

#### 10.0 RECORDS

Documentation of quality requirements and inspection shall be kept by the requestor organization until regulatory records retention requirements have been met per LIR308-00-02, "Laboratory Records Management." (<a href="http://labreq.lanl.gov/pdfs/ops/lir/LIR3080002.pdf">http://labreq.lanl.gov/pdfs/ops/lir/LIR3080002.pdf</a>) Such records shall include, but are not limited to, the following:

- Procurement: Purchase orders, specifications, drawings, requests for proposal, supplier proposals or bids, and modifications
- Inspection/acceptance: inspections or test procedures and criteria, qualification of test/inspection personnel, and conformance documentation
- Supplier: Performance records, such as inspection/test results, qualification assessments

#### 11.0 OWNERSHIP

Institutional Quality Management (PS-1/IQM) shall be the office of institutional coordination for this LIR.

#### 12.0 REFERENCES

American Society for Nondestructive Testing (ASNT)

American Society for Quality (ASQ)

American Welding Society (AWS)

BUS form 838C (Supplemental Quality Requirements)

BUS Just-in-Time http://jtprod.lanl.gov:80/

BUS Purchase Cardshttp://businternal.lanl.gov/bus5/pcard/pc1.htm

BUS Requestor Release Blanket (RRB) http://businternal.lanl.gov/bus5/reqguide/specproc/specproc.htm

BUS Requestor's Guidehttp://businternal.lanl.gov/bus5/reqguide/specproc/specproc.htm

DOE Nuclear Safety Management Rule (10CFR 830, Subpart A)

DOE Occupational Radiation Protection (10CFR 835)

DOE Order 414.1A, "Quality Assurance" Institutional Evaluated Suppliers List

(http://www.esh.lanl.gov/~esh14/Homepage/Links/forms/qsl.pdf)

FWO-SEM Construction Specifications Manual:

http://www.lanl.gov/orgs/f/f6/pubf6stds/conspec/pdfs/intro.pdf

FWO-SEM standards process contacts http://www.lanl.gov/f6stds/pubf6stds/programdirection.html

LANL Integrated Safety Management (ISM)

LANL Integrated Safeguards and Security Management (ISSM)

LANL Management Level System <a href="http://labreq.lanl.gov/pdfs/ops/lig/lig2300102.pdf">http://labreq.lanl.gov/pdfs/ops/lig/lig2300102.pdf</a>

LIR Graded Approach to Facility Work http://labreq.lanl.gov/pdfs/ops/lir/LIR2300102.pdf

LIR Laboratory Records Management Requirements

LIG 230-01-02 Graded Approach to Facility Work. (http://labreq.lanl.gov/pdfs/ops/lig/lig2300102.pdf)

Price-Anderson Amendments Act (PAAA)